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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,359	09/23/2003	Masao Matsuoka	026350-090	9190

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/667,359

Applicant(s)

MATSUOKA ET AL.

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 17-20, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-28 are pending in the application. Claims 9-16, 21-26 are withdrawn from consideration for being directed to non-elected subject matter.

This Office Action is in response to the Amendment filed on 10/31/06.

Response to Amendment

The rejection of claims 1-8, 17-20 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicant's amendment.

The declaration under 37 CFR 1.132 filed 10/31/06 is sufficient to overcome the rejection of claims 1-8, 17-19 based upon 35 U.S.C. 102 (a).

Claims 1, 4, 5, 8 and newly added claims 27 and 28 stand rejected under 35 U.S.C. 102 (b) for reasons set forth of the record mailed on 7/31/06 and further discussed below.

Claims 2, 3, 6, 7, 17-20 stand rejected under 35 U.S.C 103 (a) for reasons set forth of the record mailed on 7/31/06 and further discussed below.

Claims 1-8, 17-20, 27 and 28 are rejected under 35 U.S.C.101 for reasons discussed below.

Claims 1-8, 17-20, 27 and 28 are rejected under 35 U.S.C.112 2nd paragraph for reasons discussed below.

Response to Arguments

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinmyo et al. (US 6,229,070).

In response to the rejection, Applicants argue that the prominent feature of the invention is that the finding of ArsI has an anti-silencing effect, whereas Shinmyo et al. does not disclose this feature. Applicants assert that since an insulator does not necessarily possess the anti-silencing effect, one of ordinary skill in the art would not reasonably expect the ArsI would possess anti-silencing activity. Applicants further demonstrate other insulator that has enhancer blocking function and anti-silencing effect such as HCF1 and 5-32. Applicants thus conclude that Shinmyo do not anticipate the instant invention.

The above arguments have been fully considered but deemed unpersuasive. The instant claims are drawn to a method of protecting of a transgene from silencing, which recites a step of concurrently introducing the transgene and an insulator from sea urchin arylsulfatase into an animal, or a plant, organs of an animal or plant, or cells derived from an animal or plant. Although the preamble of the claim recites protecting of a transgene from silencing, the claim does not recite any method steps for how to achieve this goal. The method only recites a single step of “concurrently introducing the transgene and an insulator from sea urchin arylsulfatase into an animal, or a plant, organs of an animal or plant, or cells derived from an animal or plant” which is disclosed by Shinmyo et al. The anti-silencing effect of the insulator is not a limitation of the instant claims. Moreover, the claim recites an insulator of ArsI from sea urchin without set forth any specific sequence, absent evidence from the contrary, it does not distinguish from

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the insulator of ArsI disclosed by Shinmyo et al. Therefore, Shinmyo et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 3, 6, 7 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmyo et al.

Since Applicants did not provide arguments to the 103 rejection, the rejection is maintained for reasons set forth in the previous office action and answer to arguments directed to 102 rejection as discussed above.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 17-20, 27 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims recite the step of introducing a transgene and insulator sequence into an animal, including human, which read on the creation of a transgenic human. Such invention is directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Akasaka et al (Cellular and Molecular Biology, Vol.45, No.5, pages 555-565, 1999).

Akasaka et al. disclose a method of introducing a sea urchin arylsulfatase insulator with a transgene into human cell line Hela, and overcome position-dependent transgene expression in said cells (see page 560, 1st col., 3rd paragraph, and Figure 5). Although the preamble of the claims is directed to a method of prevent silencing, the claimed method step only recites one step of introducing the transgene and the insulator concurrently. As such, the Akasaka reference disclosed the instantly claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 17-20, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claims 1 and 5, the word "derived" renders the claim indefinite because the number and nature of the derivative process is unknown. As such, the metes and bounds of the claim cannot be established. Claims 2-4, 6-8, 17-20, 27 and 28 are rejected because they depend on claims 1 and 5.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
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CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'Celine X Qian', written over a horizontal line.